

## Alpha Stem Cell Clinic for the Development of Regenerative Therapies

### Grant Award Details

Alpha Stem Cell Clinic for the Development of Regenerative Therapies

**Grant Type:** Alpha Stem Cell Clinics

**Grant Number:** AC1-07764

**Project Objective:** The objective of the Alpha Stem Cell Clinics Network is to accelerate the efficient conduct of high quality stem cell clinical trials in order to support the overall CIRM mission of accelerating treatments to patients with unmet medical needs. UCSD is one of three Alpha Clinics programs currently funded by CIRM to achieve this goal. The clinic is to provide operational support to the stem cell clinical trials while creating Accelerating and Value Add Resources to accelerate and remove bottlenecks to the conduct of the trials.

**Investigator:**

<b>Name:</b>	Catriona Jamieson
<b>Institution:</b>	University of California, San Diego
<b>Type:</b>	PI

**Disease Focus:** Diabetes, Metabolic Disorders, Neurological Disorders, Spinal Cord Injury

**Human Stem Cell Use:** Adult Stem Cell, Embryonic Stem Cell

**Cell Line Generation:** Adult Stem Cell, Embryonic Stem Cell

**Award Value:** \$7,999,137

**Status:** Active

### Progress Reports

**Reporting Period:** Year 1

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**Reporting Period:** Year 2

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### Grant Application Details

**Application Title:** Alpha Stem Cell Clinic for the Development of Regenerative Therapies

**Public Abstract:** The proposed alpha clinic will bring together an outstanding team of physician-scientists with substantial clinical trials experience including stem cell and other cellular treatments of blood diseases and others. This team will also draw on our unique regional competitive advantages derived from our history of extensive collaboration with investigators at many nearby first-class research institutions and biotech companies. We propose to include these regional assets in our plans to translate our successful research on basic properties of stem cells to stem cell clinical trials and ultimately to delivery of effective and novel therapies. We propose to build an alpha clinic that serves the stem cell clinical trial needs of our large region where we are the only major academic health center with the needed expertise to establish a high impact alpha clinic. Our infrastructure will initially be developed and then used to support two major high-impact stem cell clinical trials: one in type I diabetes and one in spinal cord injury. Both are collaborations with established and well known companies. The type I diabetes trial will test embryonic stem cell derived cells that differentiate to become the missing beta cells of the pancreas. The cells are contained in a semipermeable bag that has inherent safety because of restriction of cell migration while allowing proper control of insulin levels in response to blood sugar. These hybrid devices are implanted just beneath the skin in patients in these trials. In a second trial of stem cell therapy for spinal cord injury, neuronal stem cells that have been shown to have substantial safety and efficacy in animal models of spinal cord injury and other types of spinal cord trauma or disease will be tested in human patients with chronic spinal cord injury. Both of these trials have the potential to have very substantial and important impact on patients with these diseases and the families and society that supports them. Following on these two trials, we are planning stem cell clinical trials for heart failure, cancer, ALS, and other terrible deadly disorders. Our proposed alpha clinic also benefits from very substantial leveraged institutional commitments, which will allow for an alpha clinic that is sustainable well beyond the five-year grant, which is essential to continue to manage the patients who have participated in the first trials being planned since multi-year followup and tracking is essential scientifically and ethically. We have a plan for our proposed alpha clinic to be sustainable to 10 years and beyond to the point at which these therapies if successful will be delivered to patients in our healthcare system.

**Statement of Benefit to California:** Many terrible diseases that afflict the citizens of California and cause substantial economic and emotional disruption to California families can potentially be treated with novel stem cell therapies. These therapies need to be tested in a rigorous and unbiased fashion in clinical trials, which is the focus of our proposed alpha clinic. Our clinic proposes to begin with clinical trials in two major diseases in need of improved treatment: type I diabetes and spinal cord injuries. The type I diabetes clinical trial will test a novel hybrid embryonic stem cell-derived pancreatic cell/encapsulation technology that is implanted just beneath the skin in an out-patient procedure, and is inherently safe because the cells are confined to a semi-permeable bag. The spinal cord injury trial will test the benefit of neural stem cells delivered to the site of injury. Both have substantial positive evidence in animal models and have the potential of leading to major breakthroughs. In addition to providing the infrastructure for these two trials, our proposed alpha clinic will also take advantage of very substantial regional expertise at our partner institutions to test stem cells in other diseases of importance in California including heart failure, ALS, cancer, and many others. Our proposed alpha clinic will also be a major economic as well as medical driver as it leverages substantial institutional and private sector commitment, and has the potential to deliver breakthrough therapies that will be marketed either in a health care system or by private sector companies.

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